

NOV 18 2008

5 510(k) Summary

Contact: Eli Pines, Ph D.

Device Trade Name: SyntheMed Device

Manufacturer: SyntheMed, Inc.
200 Middlesex Essex Turnpike
Suite 210
Iselin, NJ 08830

Common Name: Nasal Dressing

Classification: 21 CFR §874.4780

Class: I

Product Code: LYA

Indications For Use:

The SyntheMed Device is a fragmentable nasal dressing and is indicated for use in patients undergoing nasal/sinus surgery as a space occupying stent to separate and prevent adhesions between mucosal surfaces.

Device Description:

The SyntheMed Device ("the device") is a single use, synthetic, bioresorbable polymeric film composed of polymers used extensively in implantable, absorbable medical devices. The device comprises bis(hydroxyl)-terminated PLA-PEG-PLA triblocks, where PLA = poly(lactic acid) and PEG = poly(ethylene glycol). These PLA-PEG-PLA triblocks are chain extended to yield the device's final high molecular weight polymer. This device functions to fill nasal/sinus cavities following surgery or trauma and to keep mucosal surfaces separate during the healing process. The device leaves the site of placement by natural elimination within 4 weeks, or it may be aspirated from the cavity earlier at the discretion of the physician.

Predicate Device(s):

The SyntheMed Device is substantially equivalent to the following previously cleared devices.

1. Polyganics Nasospore (K052099)
2. Genzyme Hylasine (K012532)
3. Medtronic Xomed Meropack Nasal Dressing (K041381)

Performance Standards:

FDA has not established performance standards for this class of device.

6. Substantial Equivalence Summary

The SyntheMed Device is substantially equivalent in materials, indications, function and/or performance to the following predicate devices:

4. Polyganics Nasospore (K052099)
5. Genzyme Hylasine (K012532)
6. Medtronic Xomed Meropack Nasal Dressing (K041381)

SyntheMed, Inc believes the SyntheMed Device is substantially equivalent to the above predicates based on design, indications and intended use. SyntheMed has provided a discussion comparing the indications, the materials, and the method of action demonstrating the substantial equivalence of the SyntheMed Device.

A table comparing the subject and predicate devices is presented below.

| | SYNTHEMED DEVICE | NasoSpore | Hylasine | MeroPack |
|----------------------|--|---|---|--|
| Company | SyntheMed Inc | Polyganics | Genzyme | Medtronic/Xomed |
| 510(k)Reference | This submission | K052099 | K012532 | K041381 |
| Device name | IntraNasal Splint | IntraNasal Splint | IntraNasal Splint | IntraNasal Splint |
| Used In | Nasal/sinus surgery | Nasal/sinus surgery | Nasal/sinus surgery | Nasal/sinus surgery |
| Indications for Use | The SyntheMed Device is a fragmentable nasal dressing and is indicated for use in patients undergoing nasal/sinus surgery as a space occupying stent to separate and prevent adhesions between mucosal surfaces. | Nasopore is a fragmentable nasal dressing and is indicated for use in patients undergoing nasal/sinus surgery as a space occupying stent to separate and prevent adhesions between mucosal surfaces; to help control minimal bleeding following surgery or nasal trauma by tamponade effect and blood absorption. | HylaSine is indicated for use in patients undergoing nasal/sinus surgery as a space occupying gel stent to separate and prevent adhesions between mucosal surfaces in the nasal cavity, to help control minimal bleeding following surgery or nasal trauma, and to prevent lateralization of the middle turbinate during the post operative period. | MeroPack Tm Bioresorbable Nasal Dressing and Sinus Stent is for use in patients undergoing nasal/sinus surgery as a space occupying stent to separate and prevent adhesions between mucosal surfaces during mesothelial cell regeneration in the nasal cavity; to help control minimal bleeding following surgery or nasal trauma by tamponade effect, blood absorption and platelet aggregation; and to prevent lateralization of the middle turbinate during the postoperative period. |
| Material Composition | PLA, PEG | Fragmentable poly (DL-lactide/co caprolactone) urethane | Chemically modified hyaluronic acid and carboxymethylcellulose | Esterified hyaluronic acid and collagen |
| Method of action | Hygroscopic, fragments in contact with fluids | Hygroscopic, fragments in contact with fluids | Hygroscopic, forms gelatinous mass in contact with fluids | Hygroscopic, forms gelatinous mass in contact with fluids |
| Biocompatibility | ISO 10993 | ISO 10993 | ISO 10993 | ISO 10993 and FDA Guidance G95-1 |
| Sterile | Yes | Yes | Yes | Yes |

General Substantial Equivalence

The SyntheMed Device shares indications for the intended use with all predicate devices referenced in the above Table. The SyntheMed Device is a resorbable, synthetic polymeric material similar to Nasospore, Meropack and Hylasine.

The SyntheMed Device is applied with in a similar manner as the predicates listed. It is placed at the surgical site at the conclusion of the procedure.

Material Substantial Equivalence

The SyntheMed Device is a synthetic, resorbable polymeric film comprised of polylactic acid (PLA) and polyethylene glycol (PEG) polymers.

Polyethylene glycol (PEG) is an FDA-approved Generally Recognized as Safe (GRAS) polymer that is widely used in foods, cosmetics and pharmaceuticals, including topical, ingestible and injectable drug formulations as well as hydrogels..

PLA is an FDA-approved Generally Recognized as Safe (GRAS) polymer that is used in numerous resorbable surgical devices such as sutures, ligatures and meshes.

The SyntheMed Device biodegrades (resorbs) within a similar timeframe as the predicate devices.

Animal studies have been performed on the SyntheMed Device. These tests are described in detail in the Safety/Biocompatibility Section. The GLP studies were conducted to demonstrate and support the safety and biocompatibility of the SyntheMed Device. These studies were conducted by NaMSA under USP and ISO 10993 Guidelines.

Conclusion

The SyntheMed Device is substantially equivalent to the predicates in the nasal dressing product category. The indications, design principles and instructions for use are comparable to the referenced predicates and the SyntheMed Device shares similar indications for use language with these predicate devices. In summary, the SyntheMed Device is substantially equivalent to valid predicate nasal dressings.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 18 2008

SyntheMed, Inc.
c/o Eli Pines, Ph.D.
Vice President and Chief Scientific Officer
200 Middlesex Essex Turnpike; Suite 210
Iselin, NJ 08830

Re: K082276

Trade/Device Name: SyntheMed Device
Regulation Number: 21 CFR 874.4780
Regulation Name: Intranasal Splint
Regulatory Class: Class I
Product Code: LYA
Dated: October 27, 2008
Received: October 28, 2008

Dear Dr. Pines:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear, Nose
and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4 Indications for Use

510(k) Number (if known): K082276

Device Name: SYNTHEMED DEVICE

The SyntheMed Device is a fragmentable nasal dressing and is indicated for use in patients undergoing nasal/sinus surgery as a space occupying stent to separate and prevent adhesions between mucosal surfaces.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE
OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Daniel Cee Jr
(Division Sign-Off)

Division of Ophthalmic and Ear,
Nose and Throat Devices

510(k) Number K082276